REMARKS

Reconsideration of the present application is respectfully requested.

In the first Office Action, dated November 19, 2004, the Examiner rejected claims 1, 2, 6, 17 and 19 under 35 U.S.C. §102(b) over Brighton et al., and rejected claims 9, 10 and 14 under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) over Brighton et al.

The §102 rejection of 1, 2, 6, 17 and 19 is based on alleged inherency. Specifically, the Examiner considers the method of Brighton et al. to inherently assist in the healing of soft tissue wounds. Applicant notes in response that the title of the invention in the Brighton et al. patent is Method For Treatment of *Non-Union* Bone Fractures by Non-Invasive Electrical Stimulation (emphasis added). Brighton et al. indicates that "non-union" fractures are bone fractures that do not normally heal (col. 1, lines 9-10), and all examples of treatment according to the disclosed method involve "non-union" fractures (col. 2, line 39 et seq.). Brighton et al. does not disclose any use of the method except on patients with fractures that had failed to heal after treatment by other methods for long periods of time ranging from about six months to six years. Soft tissue wounds may well occur when a bone is broken, but such wounds presumably heal within such long periods of time. Therefore, when one practices the method as disclosed in the Brighton et al. patent, one does not necessarily treat a soft tissue wound. It is respectfully submitted that Applicant's invention as originally claimed is not anticipated by Brighton et al. on grounds of inherency.

Furthermore, claim 1 as amended recites the limitations of identifying a soft tissue wound on a subject and indicating the use of capacitively coupled electrical stimulation for treatment of the identified soft tissue wound. Brighton et al. is relevant to the use of capacitive coupling for treatment of *bone fractures*, but it does not disclose capacitively coupled electrical stimulation as an indication for treatment of soft tissue wounds. To anticipate a claim such as claim 1 as amended, the prior art must disclose an *intent to treat* the subject condition. *Eli Lilly and Company v. Teva Pharmaceuticals USA, Inc.*, 2004 U.S. Dist. LEXIS 14724 (S.D. Ind. July 29, 2004) (method of using fluoxetine to treat PMS was held to be novel because, while there were publications showing the use of fluoxetine to treat several disorders, including depression and anxiety, the prior art did not teach the use of fluoxetine for the purpose of treating mood disturbances associated with PMS) (citing *Rapoport v. Dement*, 254 F.3d 1053, 59 USPQ2d

1215 (Fed. Cir. 2001); *Jansen v. Rexall Sundown*, 342 F.3d 1329, 68 USPQ2d 1154 (Fed. Cir. 2003)).[1]

No such intent – in this case an intent to treat a soft tissue wound – is apparent in the reference cited by the Examiner. Therefore, it is respectfully submitted that claim 1 satisfies the novelty requirement of 35 U.S.C. §102. It is further submitted that neither Brighton et al. nor the prior art as a whole suggests the claimed use of capacitively coupled electrical stimulation for treatment of an identified soft tissue wound. Therefore, it is respectfully submitted that claim 1 is allowable as amended.

Independent claim 9 is hereby amend to depend from claim 1 and is believed to be allowable at least for the reasons applicable thereto. Independent claim 17 is believed to be allowable for similar reasons, as are new claims 22 and 23.

Claims 3-5, 7, 8, 11-13, 15, 16, 18, 20 and 21 are not cancelled and should be allowed along with the generic claims from which they depend.

In view of the foregoing remarks and amending changes, claims 1-23 now pending in the application are believed to be in condition for immediate allowance, and such action is respectfully requested.

The Examiner is invited to call the undersigned attorney if there are issues relating to any of the pending claims that can be addressed expeditiously by phone.

Respectfully submitted,

William F. Bahret, Reg. No. 31,087
Bahret & Associates
320 N. Meridian St., Suite 510
Indianapolis, Indiana 46204
(317) 423-2300

[1] Copies of all three court decisions enclosed.

lier unlawful activities. Indeed, were there such authority we think it would be contrary to the orderly enforcement of the trademark and copyright laws.

We conclude that the district court properly rejected Zuccarini's argument that his web sites were protected under the safe harbor provision. There was sufficient evidence for the district court to find that Zuccarini acted with a bad faith intent to profit when he registered and used the five domain names at issue here.

B.

[6] The district court correctly concluded that there is a substantial likelihood of confusion, as well as actual evidence of confusion, between Zuccarini's infringing domain names and the "Joe Cartoon" mark. In *Opticians Ass'n v. Indep. Opticians*, 920 F.2d 187, 196 [17 USPQ2d 1117] (3d Cir. 1990), a trademark infringement case, we held that a finding of irreparable injury can be based on a finding of a likelihood of confusion. The district court determined that Shields will suffer damage to his reputation and a loss of goodwill if Zuccarini is allowed to operate his offending web sites. Shields's livelihood and fame depend, in large part, on Internet users being able to access his sites, and he does not want his audience trapped in Zuccarini's sites or put off by images displayed thereon which they may attribute to him. The district court properly determined that Shields would be irreparably harmed if the court did not grant the permanent injunction.

Zuccarini testified that he has more than three thousand web sites and earns between $800,000 and $1,000,000 a year from their use. The court determined that any economic harm from the loss of the five infringing domain names would be trivial. In *Opticians Ass'n*, 920 F.2d at 197, this court held that, in trademark cases, "public interest . . . is a synonym for the right of the public not to be deceived or confused." Zuccarini admitted that he is in the business of profiting from the public's confusion and that he does, in fact, profit from this confusion. The district court properly concluded that this injunction would be in the public interest.

The district court did not err in determining that the elements for granting a permanent injunction set forth in *ACLU v. Black Horse Pike Reg'l Bd. of Educ.*, 84 F.3d 1471, 1477 nn. 2-3 (3d Cir. 1996) were satisfied, thereby entitling Shields to a permanent injunction and summary judgment on his ACPA claim.

IV.

The Act provides for statutory damages for a violation of § 1125(d)(1) "in the amount of not less than $1,000 and not more than $100,000 per domain name, as the court considers just." 15 U.S.C. § 1117(d). Zuccarini argues that § 1117(d) does not apply to him because he registered the offending domain names before the ACPA became law. The district court held that Zuccarini's continued use of the domain names after November 29, 1999 subjects him to the statute's proscriptions and remedies. We agree with the teachings of *Virtual Works, Inc. v. Volkswagen of America, Inc.*, 238 F.3d 264, 268 [57 USPQ2d 1547] (4th Cir. 2001) ("A person who unlawfully registers, traffics in, or uses a domain name after the ACPA's date of enactment, November 29, 1999, can be liable for monetary damages . . .") (emphasis added); and *E. & J. Gallo Winery v. Spider Webs Ltd.*, 129 F.Supp.2d 1033, 1047-1048 (S.D. Tex. 2001) (holding that defendant who registered domain name in bad faith could be held liable for statutory damages even though registration was prior to enactment of the ACP A when defendant continued to use web site after the enactment of the Act).

[7] In the alternative, Zuccarini argues that he only used the web site for sixty days after the passage of the ACP A and prior to this lawsuit being filed. He implies that, because he only used the web site for a short period of time, the district court's assessment of statutory damages was punitive in nature. Under the statute, the court has the discretion to award statutory damages that it "considers just" within a range from $1,000 to $100,000 per infringing domain name. *See* 15 U.S.C. § 1117(d). There is nothing in the statute that requires that the court consider the duration of the infringement when calculating statutory damages. We conclude that the district court properly exercised its discretion in awarding $10,000 for each infringing domain name.

V.

The ACPA provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 15 U.S.C. § 1117(a). In trademark infringement cases, this court has held that "a district court must make a finding of culpable conduct on the part of the losing party, such as bad faith, fraud, malice or knowing infringement before a case qualifies as 'exceptional.' " *Ferrero U.S.A., Inc. v. Ozak T rading, Inc.*, 952 F.2d 44, 47 [21 USPQ2d 1215] (3d Cir. 1991). The district court found that Zuccarini acted willfully and in bad faith when he registered the "Joe Cartoon" domain names in an effort to confuse people and to divert Internet traffic to his web sites for his own economic gain. The court found that Zuccarini conducted no bona fide business related to Joe Cartoon and that he had no basis on which to believe his use of the domain names was fair and lawful.

[8] Although the term "bad faith" is written into § 1125(d)(1)(A)(i) such that it is a threshold finding for any violation of the ACPA, we are persuaded that the district court made a proper finding that, under the circumstances, this case qualified as "exceptional" and merited the award of attorneys' fees under § 1117(a).[6] The record indicates that Zuccarini's conduct was particularly flagrant[7] and that he showed no remorse for his actions. The court stated that "based on the egregiousness of Zuccarini's conduct and his lack of contrition, we without hesitation hold that this is an 'exceptional' case and that Shields was entitled to an award of attorneys' fees." App. at A25. The court's interpretation of what constitutes an "exceptional" case under the ACPA is proper.

We have considered all contentions presented by the parties and conclude that no further discussion is necessary.

The judgment and the award of statutory damages and attorneys' fees will be affirmed.

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[6] In determining that this case is "exceptional" under § 1117(a), we do so without deciding whether the finding of "bad faith" under § 1125(d)(1)(A)(i) automatically warrants an award of attorneys' fees under § 1117(a) and the case law that has interpreted that provision. *See Ferrero U.S.A., Inc.*, 952 F.2d at 47.

[7] Between the issuance of the March 22, 2000 preliminary injunction, through the date of the determination that he violated the ACPA, and up until the date of the hearing to determine statutory damages and attorneys' fees and costs, Zuccarini registered in additional 1,644 domain names that were common misspellings of other famous companies' and/or celebrities' names.

Rapoport v. Dement

U.S. Court of Appeals
Federal Circuit
No. 00-1451
Decided June 28, 2001

PATENTS

[1] Patent construction — Claims — Broad or narrow (§ 125.1303)

Patent construction — Claims — Defining terms (§ 125.1305)

Term "treatment of sleep apneas," as used in interference count claiming method of treatment, is properly construed as referring only to reduction of frequency and severity of apnea episodes during sleep, rather than to "treatment of symptoms associated with sleep apneas" such as anxiety and depression, since ordinary meaning of term narrowly refers to treatment of underlying disorder itself, since written description defines "sleep apneas" in terms of underlying disorder, since summary of invention in senior party's application states that treatment is administered "at the hour of sleep," indicating that it is used to treat symptoms occurring during sleep, and since senior party's description of efficacy of claimed treatment method only addresses its effect on underlying disorder.

[2] Patentability/Validity — Anticipation — Identity of elements (§ 115.0704)

Patentability/Validity — Anticipation — Prior publication (§ 115.0705)

Substantial evidence supports finding by Board of Patent Appeals and Interferences that claims in senior party's application, corresponding to interference count claiming "method for treatment of sleep apneas" by administration of azapirone, were not anticipated by prior art reference, since term "treatment of sleep apneas" is properly construed as referring only to treatment of underlying respiratory disorder and not to ancillary symptom of anxiety, since publication discloses treatment of anxiety caused by sleep apnea using azapirone compound buspirone, but does not disclose treatment of sleep apnea disorder itself, since publication does not contain information regarding buspirone's effect on upper airway during sleep, or specify administration

of treatment at bedtime, since there is nothing to indicate that doses of buspirone given as directed in publication would necessarily be "therapeutically effective amount" for treatment of underlying disorder as required by count, and since senior party's invention therefore is not inherent in publication's disclosure.

[3] **Practice and procedure in Patent and Trademark Office — Interference — Pleadings and submissions (§ 110.1706)**

Practice and procedure in Patent and Trademark Office — Interference — Motions (§ 110.1717)

Junior party's motion for acceptance of belated filing, in which junior party alleged that prior invention of claims by different inventive entity either anticipated or rendered obvious senior party's claims, was properly denied, since notice of interference should have made junior party aware that senior party had priority benefit of abandoned application, since senior party's notification should have made junior party aware that senior party was obligated to assign interests to other entities, and since junior party did not show sufficient cause why his motion was not filed sooner.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent interference proceeding (no. 102,760) between David M. Rapoport, junior party, and William C. Dement, Mark R. Rosekind, and Jeffrey L. Schwimmer, senior party. Junior party appeals from board's finding that senior party's claims corresponding to count were not anticipated nor rendered obvious by prior art, and from denial of motion to accept belated finding and dismissal of belated motion for judgment. Affirmed.

Roger L. Browdy, of Browdy and Neimark, Washington, D.C., for appellant.

David S. Abrams and Robert H. Berdo, of Roylance, Abrams, Berdo & Goodman, Washington, for appellee.

Before Clevenger, Rader, and Gajarsa, circuit judges.

Clevenger, J.

David M. Rapoport ("Rapoport") appeals from a final decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office ("Board") dated February 29, 2000. The real parties in interest in this interference are: (1) New York University ("NYU"), assignee of Rapoport; (2) the Board of Trustees of the Leland Stanford Junior University ("Stanford"), assignee of William C. Dement ("Dement") and Mark R. Rosekind ("Rosekind"); and (3) the Bristol-Myers Squibb Company ("Bristol-Myers"), assignee of Jeffrey L. Schwimmer ("Schwimmer"). Collectively, Dement, Rosekind, and Schwimmer will be referred to herein as "Dement et al."

The Board awarded judgment of priority as to the sole count of the interference in favor of Dement *et al.*, and further ordered that Dement *et al.* are entitled to a patent containing claims 1-13 of U.S. Patent Application No. 07/695,325 ("the '325 application"), filed May 3, 1991, and that Rapoport is not entitled to a patent containing claims 1-12 of U.S. Patent Application No. 07/479,693 ("the '693 application"), filed February 14, 1990. We affirm.

I

The subject matter at issue in this case is a method for the treatment of sleep apnea. Generally, sleep apnea refers to the transient cessation of breathing during sleep. As described by the Board:

> Sleep apneas comprise a spectrum of disorders with varying severity and morbidity and are usually classified as being an obstructive, central, or mixed apnea, depending on the presence or absence of respiratory efforts during the periods in which airflow has ceased. Obstructive and mixed apneas occur with greatest frequency with the most familiar being obstructive sleep apnea syndrome in which sporadic recurring collapse of the patient's upper airway occurs during sleep. If the collapse is complete, there is no air exchange at the nose and mouth and breathing is interrupted. The usual result is a partial arousal and a return to normal breathing.

In most instances, patients suffering from sleep apnea have no knowledge or memory of the apnea episodes, but find themselves constantly suffering from fatigue and daytime drowsiness for no apparent reason. Consequently, due to this chronic lack of proper rest, patients who suffer from sleep apnea often exhibit secondary symptoms of anxiety, depression, fatigue, malaise, irritability, anger, hostility, and other similar problems.

The count in this interference relates to the treatment of sleep apnea by administering a therapeutically effective amount of certain azapirone compounds such as buspirone "to a patient in need of such treatment."

On February 12, 1990, Schwimmer filed U.S. Patent Application No. 07/478,820 ("the '820 application"). Claim 1 of the '820 application as originally filed reads in relevant part:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

There is no dispute that although buspirone is an azapirone compound, the azapirone compounds of Schwimmer's Formula I exclude buspirone. On the same day, Dement, Rosekind, and Schwimmer jointly filed U.S. Patent Application No. 07/479,803 ("the '803 application"). Original claim 1 of the '803 application reads as follows in its entirety:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of buspirone or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment.

Two days later, on February 14, 1990, Rapoport filed the '693 application. Claim 1 of the '693 application reads as follows in relevant part:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

The azapirone compounds of Rapoport's Formula I include buspirone, and claim 6 of Rapoport's '693 application is specifically directed to buspirone.

On February 12, 1991, Schwimmer filed U.S. Patent Application No. 07/657,332 ("the '332 application") as a continuation of the '820 application, and on May 3, 1991, Dement, Rosekind, and Schwimmer jointly filed the '325 application as a continuation-in-part of the '803 and '332 applications. Original claim 1 of the '325 application reads as follows in relevant part:

> 1. A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

The azapirone compounds of Formula I in the context of the '325 application include buspirone, and claim 7 of the '325 application is specifically directed to buspirone.

On January 10, 1992, an interference was declared, and Dement *et al.* were accorded the benefit of the February 12, 1990, filing date of the '820 and '803 parent applications and therefore designated as the senior party. Count 1 of the interference, the only count at issue, reads in pertinent part as follows:

> A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

The azapirone compounds of Formula I in the context of the interference count include buspirone. Claims 1-12 of Rapoport's '693 application and claims 1-13 of the Dement *et al.* '325 application correspond to the count.

On June 10, 1992, Rapoport filed a Motion for Judgment pursuant to 37 C.F.R. § 1.633(a) in which he argued, *inter alia*, that the subject matter of the count was not patentable to Dement *et al.*, on the grounds that it was anticipated and/or rendered obvious pursuant to 35 U.S.C. § 102(a) and/or 35 U.S.C. § 103 by a prior art reference authored by Rapoport. This reference, entitled "Buspirone: Anxiolytic Therapy with Respiratory Implications," was published in *Family Practice Recertification* in September 1989, at pages 32-37 of Vol. 11, No. 9 (Supplement) ("the FPR Publication"). We note that the FPR Publication does not constitute a statutory bar against either Dement *et al.* or Rapoport, since it was published less than one year before the priority filing date of the '325 and '693 applications. 35 U.S.C. §§ 102(a) and 102(b) (1994). However, because the FPR Publication was authored by Rapoport, it can be cited as prior art against Dement *et al.*, but not against Rapoport. 35 U.S.C. § 102 (1994); *In re Katz*, 687 F.2d 450, 454, 215 USPQ 14, 17 (CCPA

1982). Dement *et al.* do not contest the fact that the FPR Publication is a prior art reference that may be cited against them in this interference.

On October 29, 1992, pursuant to 37 C.F.R. § 1.602(b), Dement and Rosekind disclosed that they were obligated to assign their rights in the '325 application to Stanford, and Schwimmer disclosed that he was obligated to assign his rights to Bristol-Myers. Approximately eight months later, on June 21, 1993, Dement *et al.* explicitly stated on the record that Schwimmer was the sole inventor of the use of most of the azapirone compounds covered by the count except for buspirone in the treatment of sleep apnea. On July 9, 1993, Rapoport filed a Second Motion to Accept Belated Filing Of Preliminary Motion Under 37 C.F.R. § 1.633(a) ("Rapoport's Motion to Accept Belated Filing") along with a Motion for Judgment Under C.F.R. § 1.633(a) ("Rapoport's Belated Motion for Judgment") arguing that claims in the Dement *et al.* '325 application are unpatentable under 35 U.S.C. § 102(g) and/or § 103 over the prior invention of claims 7 and 13 of Dr. Dement, which were invented by a different inventive entity.

On April 12, 1996, the Board rendered a decision which, *inter alia*, denied Rapoport's June 10, 1992, Motion for Judgment, denied Rapoport's Motion To Accept Belated Filing, and dismissed Rapoport's Belated Motion for Judgment as being untimely. These decisions were adhered to in a decision for reconsideration dated September 6, 1996. The Board rendered its final decision on February 29, 2000.

In its decision dated April 12, 1996, the Board found that: (1) Rapoport had established a conception date of May 13, 1988; (2) Dement was entitled to a 1986 date of conception; and (3) the conception by Dement inures to the benefit of Dement *et al.* pursuant to 35 U.S.C. § 116. Based on these findings, the Board awarded priority of the invention of the interference count to Dement *et al.* Before this court, Rapoport does not contest either the ultimate priority determination in favor of Dement *et al.* or the underlying findings by the Board.

Instead, on appeal Rapoport argues that the Board erred in not finding that all of the Dement *et al.* claims corresponding to the count are either anticipated by the FPR Publication or rendered obvious by the FPR Publication in combination with admissions allegedly made in the Dement *et al.* '325 application. Rapoport also argues that it was an abuse of discretion for the Board to deny Rapoport's Motion to Accept Belated Filing and to dismiss Rapoport's Belated Motion for Judgment as being untimely. Finally, Rapoport argues that—in the event that this court finds that all of the Dement *et al.* claims are unpatentable in view of the FPR Publication—the Board erred in awarding judgment on priority in favor of Dement *et al.* We have jurisdiction to hear this appeal pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994) and 35 U.S.C. § 141 (1994).

II

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Anticipation is a question of fact, and we uphold decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. *In re Hyatt*, 211 F.3d 1367, 1371-72, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced. *In re Schreiber*, 128 F.3d at 1477, 44 USPQ2d at 1431. The Board's determination of obviousness is a question of law subject to *de novo* review. However, the Board's factual determinations underlying its rulings on anticipation and obviousness are reviewed under the substantial evidence test. *Dickinson v. Zurko*, 527 U.S. 150, 50 USPQ2d 1930 (1999); *In re Gartside*, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1775-76 (Fed. Cir. 2000). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Gartside*, 203 F.3d at 1312, 53 USPQ2d at 1773 (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)).

The Board's decisions to deny Rapoport's Motion to Accept Belated Filing and to dismiss Rapoport's Belated Motion for Judgment are reviewed for abuse of discretion. *Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050-51, 29 USPQ2d 1615, 1617 (Fed. Cir. 1994). An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision. *Id.*

As noted above, Rapoport has not requested review of the underlying factual determinations or of the legal bases for the Board's award of priority to Dement *et al.* Instead, Rapoport merely questions the Board's action of awarding priority to Dement *et al.* at the same time as holding the Dement *et al.* claims patentable. This issue involves the Board's legal conclusions regarding priority, conception and reduction to practice, which we review *de novo*. *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000).

III

We first address Rapoport's argument that the Dement *et al.* claims corresponding to the count are anticipated by the FPR Publication. Because the first step of a patentability or invalidity analysis based on anticipation and/or obviousness in view of prior art references is no different from that of an infringement analysis, we must start by interpreting any disputed terms in the interference count. *Amazon.com, Inc. v. barnesandnoble.com, inc.*, 239 F.3d 1343, 1351, 57 USPQ2d 1747, 1751-52 (Fed. Cir. 2001). Only when a claim is properly understood can a determination be made whether the claim "reads on" an accused device or method, or whether the prior art anticipates and/or renders obvious the claimed invention. *Id.*

A

Rapoport argues on appeal, as he did before the Board, that it is reasonable to interpret the phrase "method for treatment of sleep apneas" in the interference count broadly to include both (1) treatment of anxiety secondary to sleep apnea and (2) treatment of the underlying sleep disorder itself. In contrast, Dement *et al.* agree with the Board, which found that in the context of the present interference, treatment of the underlying sleep apnea disorder itself is distinct from treatment of anxiety and other secondary symptoms related to sleep apnea. Based on this finding, the Board interpreted the term "treatment of sleep apneas" in the interference count as being limited to treatment of the underlying sleep apnea disorder itself. We review the Board's legal conclusion, as we do all rulings on claim interpretation, without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174-75 (Fed. Cir. 1998) (en banc); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 USPQ2d 1321, 1329 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 38 USPQ2d 1461 (1996). Upon reviewing the record, we discern no error with the Board's interpretation.

First, we note that the disputed phrase "treatment of sleep apneas" is technically part of the preamble of the interference count, because it appears before the transition word "comprising." However, there is no dispute in this case that the phrase should be treated as a claim limitation. Moreover, without treating the phrase "treatment of sleep apneas" as a claim limitation, the phrase "to a patient in need of such treatment" would not have a proper antecedent basis.

[1] In support of his proposed broad interpretation for "treatment of sleep apneas," Rapoport relies on the following passage from the written description of the Dement *et al.* '325 application:

> There are two aspects to the use of azapirones in treating sleep apneas. The first is that the administration of an azapirone effectively reduces the frequency and severity of the apnea episodes during sleep. This is reflected in significantly increased undisturbed sleep and a significant increase in blood oxygen levels. The second aspect involves azapirone alleviation of the symptomatology associated with the occurrence of sleep apneas. The azapirone treatment alleviates the sleep apnea-related symptoms of anxiety, depression, fatigue, malaise, irritability, anger and hostility.

According to Rapoport, this passage supports the notion that "treatment of sleep apneas" in the interference count should include both treatment of the underlying disorder and the "symptomatology associated with the occurrence of sleep apneas." However, to the extent that the above passage suggests that "alleviation of the symptomatology associated with the occurrence of sleep apneas" constitutes an aspect of the use of azapirones in treating sleep apneas, the intrinsic record in this case leads to the conclusion that "treatment of sleep apneas" refers only to treatment of the underlying sleep apnea disorder.

First, the plain language of the interference count unambiguously refers to "treatment of sleep apneas" narrowly defined, and does not also include by its plain terms "treatment of

symptoms associated with sleep apneas." *See Davis v. Loesch*, 998 F.2d 963, 968, 27 USPQ2d 1440, 1444 (Fed. Cir. 1993) ("Interference counts are given the broadest reasonable interpretation possible, and resort to the specification is necessary only when there are ambiguities inherent in the claim language or obvious from arguments of counsel.") (citations omitted); *In re Hyatt*, 211 F.3d at 1372, 54 USPQ2d at 1667 (during examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification). Here, Rapoport relies on the written description of the Dement *et al.* '325 application in an unsuccessful attempt to broaden the phrase "treatment of sleep apneas" from its ordinary meaning, which narrowly refers to treatment of the underlying disorder itself.

Contrary to Rapoport's assertions, the written description of the Dement *et al.* '325 application actually confirms the Board's interpretation, and explicitly defines "sleep apneas":

> In the context of this invention, sleep apneas comprise all the sub-categories such as those caused by upper airway obstruction; those whose origins arise in the central nervous system; and those of a mixed type with contribution from both components.

This passage indicates that the term "treatment of sleep apneas" refers to reducing or eliminating sleep apneas caused by upper airway obstructions, sleep apneas whose origins arise in the central nervous system, and sleep apneas of a mixed type.

As further support for the Board's position, the Summary of the Invention in the Dement *et al.* '325 application states that "[f]or use in the instant method oral administration of a dose of from about 10 to 60 mg of an azapirone at the hour of sleep is usually employed." This description is consistent with treatment of the underlying sleep apnea disorder, which by definition manifests itself during sleep, and inconsistent with treatment of anxiety and other symptoms commonly associated with sleep apnea, which would obviously manifest themselves while a patient is awake.

Next, in a portion of the Detailed Description of the Invention not limited to any particular embodiment, the Dement *et al.* '325 application states as follows:

> [T]he present invention concerns a method for treating sleep apneas comprising obstructive, central and mixed apneas, in a patient population that ranges from infants to geriatric-aged individuals.

Once again, this passage defines sleep apneas in terms of the underlying respiratory disorder and uses the term "treating sleep apneas" in a manner that is consistent with the Board's interpretation.

Finally, when describing the effectiveness of the sleep apnea treatment method that is disclosed and claimed in the Dement *et al.* '325 application, the discussion is limited to the treatment's effect on the underlying sleep apnea disorder, and does not mention the treatment's effect on the associated symptomatology:

> The effectiveness of azapirone treatment of patients suffering from sleep apneas can be exemplified by clinical experience with buspirone. Single dose administration of buspirone, given at bedtime to patients suffering from obstructive sleep apnea, resulted in increased sleep efficiency with experimentally derived measurements showing a gain in total sleep time and a marked reduction in episodes of sleep disturbance. One of the most consistent physiological measurements of improvement was a 10 to 20% increase in blood oxygen levels, an indication of improved respiratory efficiency.

In other words, Dement *et al.* noted that treating patients suffering from obstructive sleep apnea with buspirone at bedtime had a measurably beneficial effect on the underlying sleep apnea disorder (*i.e.*, increased sleep efficiency, gain in total sleep time, significant reduction in episodes of sleep disturbance, and improved respiratory efficiency). However, Dement *et al.* made no mention in the written description of the '325 application of specific evidence of the treatment's effect on the symptomatology commonly associated with sleep apnea.

We therefore conclude that the Board was correct in interpreting "treatment of sleep apneas" as being limited to treatment of the underlying sleep apnea disorder, *i.e.*, reducing the frequency and severity of the apnea episodes during sleep.

B

Having construed the disputed term in the interference count and affirmed the Board's

interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. What a reference teaches is a question of fact. *In re Beattie*, 974 F.2d 1309, 1311, 24 USPQ2d 1040, 1041-42 (Fed. Cir. 1992). Therefore, we review the Board's characterization of the disclosure in the FPR Publication for substantial evidence. *In re Gartside*, 203 F.3d at 1316, 53 USPQ2d at 1775-76. The record indicates that substantial evidence supports the Board's factual findings regarding the FPR Publication.

[2] There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition. As the Board correctly found, the FPR Publication focuses on the treatment of anxiety with buspirone, and indicates that buspirone has potential as a primary treatment for dyspnea (which simply refers to difficulty in breathing in general).

For example, a passage in the FPR Publication mentions the possibility of administering buspirone to patents suffering from sleep apnea, but this is for the purpose of treating anxiety in such patients, not for the purpose of treating the sleep apnea disorder itself:

> Buspirone thus appears to be an anxiolytic agent with a profile of respiratory effects that make it potentially safer to use for patients with impaired respiratory function and for patients with diseases such as obstructive sleep apnea, when use of ventilatory depressants would be clearly dangerous.

Rapoport concedes as much:

> While this passage does not disclose administering buspirone with the intent of treating the sleep apnea *per se*, such an explicit intent is not necessary in order to anticipate the claims of Dement corresponding to the count.

Rapoport Opening Brief before the Board filed July 5, 1994. In a nutshell, using Rapoport's own words from its Opening Brief before the Board, Rapoport's theory on anticipation is as follows:

> As long as one administers buspirone to a patient with sleep apnea in a therapeutically effective amount, at least claims 1, 2, 6 and 7 of the Dement et al [sic] application underlying the present proceeding are fully anticipated.

In other words, according to Rapoport, neither the reasons for administering buspirone to the patient nor the time of administration are relevant. Instead, according to Rapoport, the only requirement of the count is that the patient suffer from sleep apnea. Given our disagreement with Rapoport's proposed claim interpretation, this argument cannot succeed.

Moreover, the need for tests to confirm safety for treating anxiety in patients with sleep apnea is indicated in the very next sentence of the FPR Publication relating to treating patients suffering from anxiety: "The preliminary results found among healthy subjects need to be confirmed by directly testing patients who need anxiolytic therapy." Thus, even the *proposed* testing in the FPR Publication is limited to the treatment of patients suffering from anxiety, not from sleep apnea. Moreover, the lack of information concerning administration of buspirone to patients while sleeping is indicated in Table 3 of the FPR Publication, where the entry under "Buspirone" regarding its effect on upper airway tone during sleep is "Undetermined."

The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea. Rather, the FPR Publication discloses administering single oral doses of 10 mg to nine normal volunteers. It also discloses administering buspirone in an amount of 10 mg three times a day to two patients with "severe alveolar hypoventilation" who needed anxiolytic therapy to facilitate use of a nocturnal ventilator. There is no dispute that none of these patients are reported as suffering from sleep apnea in the FPR Publication.

In contrast, as mentioned earlier, the Dement *et al.* '325 application discloses that based on clinical experience, administration of a single dose of buspirone at bedtime to patients suffering from obstructive sleep apnea resulted in a marked reduction in episodes of sleep disturbance, and further discloses administration of 20-40 mg of buspirone at the hour of sleep to an average adult.

We note that there is no mention in the FRP Publication of administering buspirone to a patient at bedtime. The significance of this

fact, of course, is that sleep apnea, by definition, occurs during sleep. In one of the two tests mentioned in the FPR Publication, a single 10 mg dosage was given at an unspecified time, while in the second test buspirone was administered in doses of 10 mg three times a day, once again without specifying administering the buspirone at bedtime.

Finally, we note that Rapoport argues that the FPR Publication inherently anticipates the count even under the Board's claim interpretation. *See In re Graves*, 69 F.3d 1147, 1152, 36 USPQ2d 1697, 1701 (Fed. Cir. 1995) (noting that a reference anticipates a claim if it discloses the claimed invention such that a skilled artisan could take the teachings of the reference in combination with his own knowledge of the particular art and be in possession of the invention) (citations omitted). According to Rapoport:

> The anxiolytic amount of buspirone taught by the *FPR* publication still inherently anticipates in view of the fact that the Dement et al. application contains disclosures that anxiolytic amounts of buspirone overlap the preferred therapeutically effective amounts of buspirone disclosed in the Dement et al. application for reducing the frequency and severity of the apnea episodes during sleep.

Specifically, Rapoport bases his argument on the observation that the Dement *et al.* application specifies administration of buspirone at the hour of sleep in dosages of about 20-40 mg for an average adult. Next, Rapoport notes that the FPR Publication discloses a dosage of 10 mg of buspirone three times a day for treatment of anxiety. The conclusion to be drawn from these observations, according to Rapoport, is as follows:

> The fact that the Dement et al. specification recites a preferred range of 20-40 mg of buspirone administered at the time of sleep does not suggest that the administration of 10 mg of buspirone at the time of sleep, particularly when there have been two other dosages of 10 mg each during the course of the day, will have no therapeutic effect. The claims do not require optimal amounts, only therapeutically effective amounts. If 10 mg of buspirone has any effect on the treatment of sleep apnea, even if not optimum, the claim is anticipated.

We conclude that Rapoport's inherency argument is without merit. First, Rapoport neglects to point out that the FPR Publication explicitly states that the patients who received the 10 mg doses of buspirone three times a day were suffering from "severe alveolar hypoventilation who needed anxiolytic therapy to facilitate the use of a nocturnal ventilator," not from sleep apnea. Second, Rapoport's argument is based on at least two speculative assumptions: (1) that a treatment regimen of three doses a day would necessarily include an administration "at the time of sleep;" and (2) that administering two 10 mg doses of buspirone at unspecified times throughout the day in conjunction with a 10 mg dose of buspirone at bedtime would necessarily result in a "therapeutically effective amount" of buspirone treatment for the purpose of treating the underlying sleep apnea disorder. "Inherency," however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis in original) (citations omitted). Rapoport has not attempted to demonstrate that the proposed dosage regimen in the FPR Publication would necessarily result in a therapeutically effective amount. Instead, Rapoport merely argues that the "preferred" range of 20-40 mg described in the Dement *et al.* application does not rule out the thrice-daily 10 mg doses of buspirone discussed in the FPR Publication in the context of patients who are not even described as suffering from sleep apnea. The burden of proof, of course, is on Rapoport, by a preponderance of the evidence. *Brining v. Hirose*, 161 F.3d 681, 685-86, 48 USPQ2d 1934, 1937-38 (Fed. Cir. 1998) (copending applications invoke the preponderance of the evidence standard).

Most importantly, however, as we noted at the outset the issue of anticipation—whether by inherency or otherwise—is a question of fact, and we uphold decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. *In re Hyatt*, 211 F.3d at 1371-72, 54 USPQ2d at 1667. In this case, as detailed above, our review of the record indicates that the Board's findings are amply supported by the evidence. The Board considered the evidence of record and correctly ruled against Rapoport on this issue.

Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

IV

Next, we address Rapoport's argument that the Board's action of denying Rapoport's Motion to Accept Belated Filing was an abuse of discretion. As noted earlier, this motion alleged that the Dement *et al.* claims are either anticipated under 35 U.S.C. § 102(g) and/or rendered obvious under 35 U.S.C. § 102(g) and/or § 103 over the prior invention of claims 7 and 13 of Dr. Dement, which were invented by a different inventive entity.

[3] Our review of the record indicates that the Board denied the Motion to Accept Belated Filing on the basis that Rapoport had filed it on July 9, 1993, approximately eight months after Rapoport should have been aware of the facts upon which the motion was based. As the Board correctly noted, Rapoport should have been aware when the interference was declared that the notice of interference accorded Dement *et al.* the benefit of the abandoned '820 application, wherein Dr. Schwimmer signed an oath stating that he is the sole inventor of the claimed subject matter (*i.e.*, using azapirones other than buspirone to treat sleep apnea). Moreover, the Board correctly indicated that Rapoport learned or should have been aware of the grounds of unpatentability urged in the preliminary motion for judgment on or about October 29, 1992, when Dement *et al.* filed a notification pursuant to 37 C.F.R. § 1.602(b) stating that Drs. Dement and Rosenkind were obligated to assign their entire interest to Stanford and that Dr. Schwimmer was obligated to assign his entire interest to Bristol-Myers.

In view of the above, we conclude that the Board did not abuse its discretion by denying Rapoport's Motion to Accept Belated Filing or in dismissing the preliminary motion for judgment, because there is evidence of record upon which the Board could base its decision that Rapoport did not show "sufficient cause" why the motion was not filed sooner, as required by 37 C.F.R. § 1.645(b).

V

Finally, we turn to Rapoport's argument that the Board erred in awarding judgment on priority in favor of Dement et al. against Rapoport, notwithstanding the possibility that all of the Dement *et al.* claims could be ruled unpatentable to Dement *et al.* As Rapoport acknowledges, we need not reach this issue, given our conclusion that the Board did not err in finding that the Dement *et al.* claims were not rendered unpatentable by the FPR Publication.

VI

For the reasons set forth above, the decision of the Board is, in all respects,

AFFIRMED.

Earth Flag Ltd. v. Alamo Flag Co.

U.S. District Court
Southern District of New York
No. 00 Civ. 3961 (SAS)
Decided May 17, 2001

COPYRIGHTS

[1] Elements of copyright — Statutory elements — Originality (§ 205.0707)

Plaintiff's "Earth Flag," which consists of two identical circular photographs of Earth taken from space, sewn onto each side of dark blue synthetic fabric, has no non-trivial, original component that entitles it to copyright protection, since work is nothing more than public domain photograph transferred from medium of paper to medium of fabric, and fact that reproduction in new medium of fabric required some skill and vision does not render flag protectable, and since none of remaining features of flag contain any original expression.

[2] Elements of copyright — Statutory elements — Originality (§ 205.0707)

Plaintiff's "Earth Flag," which lacks any non-trivial, original component, is not entitled to copyright protection, since work and energy expended in developing flag, filing certificates of registration, and marketing it and popularizing it as symbol for environmental movement neither demonstrate "true artistic skill" nor contribute to flag's protectability.

its affirmative defenses relating to the non-ringement of the '774 and '109 patents.[7] s sanction is the only one appropriate to er Waterloo from future misconduct while the same time protecting Ciba and ad-iately remedying its harm. The effect of remedy is a finding that Waterloo in-iged Ciba's patent, leaving only the issue of nages to be resolved by this Court.

Ciba also moves the Court for attorneys s and costs. "[T]he 'less severe sanction' an assessment of attorney's fees is undoubt-y within a court's inherent power. . . ." *ambers*, 501 U.S. at 45. Accordingly, the urt also permits Ciba to file an application attorneys' fees and for any additional costs urred as a result of this fraud upon the rt.

IV.

For the foregoing reasons, Plaintiff's Mo-n Expedited Conference on Defendants' parent Fraud Upon the Court (Doc. #26), nstrued herein as a Motion for Sanctions, is *RANTED*. The Court *STRIKES* Defendant terloo's affirmative defenses and dismisses counter-claims.[8]

IT IS SO ORDERED.

ORDER

On *AUGUST 28, 2003 at 10:00 A.M.:*

MR. DENTON BOWMAN shall appear and ow cause why he should not be held in con-npt for perpetrating a fraud upon this Court. e Court urges Mr. Bowman to retain his vn counsel. Although he testified that he is Executive Vice President of Waterloo Coal ompany, nonetheless, if Mr. Bowman con-nds that he does not have sufficient financial sources to retain his own independent coun-l, he shall so notify the Court in writing thin ten (10) days of the date of this Order. If Mr. Bowman provides such written notification, the Court will consider appointing an attorney for him for purposes of this Show Cause Hearing.

IT IS SO ORDERED.

[7] The Court does not by this ruling pass on the validity or enforceability of the '774 or '109 patents. *See Apotex Corp. v. Quickturn Design Sys.*, 269 F.3d 1369 [60 USPQ2d 1705] (Fed. Cir. 2001) (holding that courts are free to sanction bad faith conduct but may not invalidate the patent as part of sanction).

[8] Because Plaintiff has not suggested and no evidence presented at the hearing supports the conclusion that either of the two remaining Defendants participated in the fraud, this matter will proceed to hearing with respect to Defendants Zinkan Enterprises, Inc. and Albert Fairchild, Jr.

Jansen v. Rexall Sundown Inc.

U.S. Court of Appeals
Federal Circuit

No. 03-1069

Decided September 8, 2003

PATENTS

[1] Patent construction — Prosecution history estoppel (§ 125.09)

Patent construction — Claims — Broad or narrow (§ 125.1303)

Claims for method of "treating or preventing" pernicious anemia by administering folic acid and vitamin B_{12} "to a human in need thereof" are properly construed to require that compound be administered to human with recognized need to treat or prevent anemia, since "treating or preventing" phrase in preambles sets forth objective of claimed method, and body of claim directs that method be performed on subject "in need," and since prosecution history supports this construction, in that patentability hinged upon addition of phrases to claim language, and phrases were added simultaneously, and should be read together; thus, claimed method is not practiced if claimed vitamins in claimed doses are administered for some purpose other than treating pernicious anemia.

[2] Infringement — Construction of claims (§ 120.03)

Infringement — Literal infringement (§ 120.05)

Federal district court properly granted summary judgment that administration of defendant's over-the-counter dietary supplement does not infringe claimed method of "treating or preventing" pernicious anemia by administering folic acid and vitamin B_{12} "to a human in need thereof," even though amounts of folic acid and vitamin B_{12} in accused supplement are within ranges claimed in patent, since asserted claims are properly construed to require that compound be administered to human with recognized need to treat or prevent anemia, since, without evidence that accused product is prescribed by medical doctors, plaintiff has shown no more than theoretical possibility that defendant's customers take accused product knowingly to treat pernicious anemia, and since such "metaphysical doubt" is insufficient to raise genuine issue of material fact.

Particular patents — Chemical — Vitamins

4,945,083, Jansen, safe oral folic-acid-containing vitamin preparation, summary judgment of noninfringement affirmed.

Appeal from the U.S. District Court for the Southern District of Indiana, Tinder, J.

Action by Christian J. Jansen Jr. against Rexall Sundown Inc. for contributory patent infringement and inducement. Plaintiff appeals from summary judgment of noninfringement. Affirmed.

John C. McNett and Steve E. Zlatos, of Woodard, Emhardt, Naughton, Moriarty & McNett, Indianapolis, Ind., for plaintiff-appellant.

Gary H. Levin and Lynn B. Morreale, of Woodcock Washburn, Philadelphia, Pa., for defendant-appellee.

Before Lourie, Rader, and Schall, circuit judges.

Lourie, J.

Christian J. Jansen, Jr., appeals from the final decision of the United States District Court for the Southern District of Indiana granting summary judgment that Rexall Sundown, Inc. has not infringed Jansen's U.S. Patent 4,945,083. *Jansen v. Rexall Sundown, Inc.*, No. IP 00-1495-C-T/G (S.D. Ind. Sept. 25, 2002). Because the court correctly construed the patent claims and correctly found no genuine issues of material fact on the question of infringement, we affirm.

BACKGROUND

Jansen is the sole inventor and owner of the '083 patent, which is directed to methods of "treating or preventing macrocytic-megaloblastic anemia" by administering a combination of folic acid and vitamin B_{12} "to a human in need thereof." '083 patent, col. 6, ll. 20-24, ll. 37-41. According to the patent, deficiencies of either folic acid or vitamin B_{12} can cause macrocytic-megaloblastic anemia, also referred to as pernicious anemia, while a deficiency of vitamin B_{12} can also cause neurological problems. *Id.* at col. 4, ll. 13-25. When folic acid alone is utilized to treat macrocytic-megaloblastic anemia, the folic acid may mask a vitamin B_{12} deficiency. *Id.*; *see also id.* at col. 3, l. 65 – col. 4, l. 5. An objective of Jansen's invention is to administer both supplements together to avoid the masking problem. *Id.* at col. 4, ll. 25-48. The independent claims read as follows:

> 1. A method of *treating or preventing macrocytic-megaloblastic anemia* in humans which anemia is caused by either folic acid deficiency or by vitamin B_{12} deficiency which comprises administering a daily oral dosage of a vitamin preparation *to a human in need thereof* comprising at least about 0.5 mg. of vitamin B_{12} and at least about 0.5 mg. of folic acid.
>
> 4. A method of *treating or preventing macrocytic-magaloblastic [sic] anemia* in humans which anemia is caused by either folic acid deficiency or by vitamin B_{12} deficiency which comprises orally administering combined vitamin B_{12} and folic acid *to a human in need thereof* in sufficient amounts to achieve an oral administration of at least about 0.5 mg. of vitamin B_{12} and at least about 0.5 mg. of folic acid within one day.

Id. at col. 6, ll. 20-24, ll. 37-41 (emphases added).

The '083 patent is a seventh-generation continuation of a patent application filed in 1970. Every member of the '083 patent's lineage was abandoned in favor of the succeeding application until the '083 patent issued in 1990. Jansen's first application claimed the method as follows:

> A method of treating or preventing anemia in humans which comprises administering a daily oral dosage of a vitamin preparation containing at least .5 mg. of vitamin B_{12} and at least .5 mg. of folic acid, whereby anemia can safely be treated orally without determining whether it is caused by folic

acid deficiency or by vitamin B_{12} deficiency.

In re Jansen, 187 USPQ 743, 744 (CCPA 1975). That original claim, while specifying approximately the same amounts of folic acid and vitamin B_{12}, does not specify the type of anemia being treated and says nothing about any need on the part of the human subject. The U.S. Patent and Trademark Office ("PTO") found that claim, as well as claims directed to the composition of matter, to be obvious in light of prior art that taught administration of folic acid alone in the claimed range, vitamin B_{12} alone in the claimed range, and combinations of the two in smaller doses than claimed. The PTO found unpersuasive Jansen's argument that administration of both components in the higher, claimed doses was an unexpected solution to the masking problem, and the Court of Customs and Patent Appeals affirmed the PTO's rejections. *Id.* at 746. In his next five applications, Jansen persistently attempted to gain allowance of his claims in slightly different form, yet the PTO consistently rejected his attempts. In the prosecution of his seventh application, Jansen repeated his masking-avoidance argument and submitted an article that asserted that the medical community had come to realize the effectiveness of folic acid-vitamin B_{12} combination therapy to treat pernicious anemia only after Jansen's invention date. *See* William H. Crosby, *Improvisation Revisited—Oral Cyanocobalamin Without Intrinsic Factor for Pernicious Anemia*, 140 Arch. Intern. Med. 1582 (1980). The examiner agreed but noted that the claims, being directed to unspecified anemia, were not commensurate in scope with Jansen's showing of unexpected results. Jansen thereafter agreed to cancel his composition of matter claims and to narrow his method claims by requiring a specific type of anemia, *viz.*, macrocytic-megaloblastic anemia, rather than anemia generally, and by adding to the claims the phrase "to a human in need thereof." The PTO then issued the '083 patent to Jansen.

Rexall markets to the general public an over-the-counter dietary supplement presently known as Folic Acid XTRA™ that contains folic acid and vitamin B_{12} within the claimed ranges. The Rexall product is labeled and advertised for maintenance of proper blood homocysteine level, but not for prevention or treatment of macrocytic-megaloblastic anemia.

Jansen sued Rexall for inducement of and contributory infringement of the '083 patent. In the district court Jansen argued that all people are "human[s] in need" of "treat[ment] or prevent[ion] of macrocytic-megaloblastic anemia," but the court, without definitively construing the "in need" phrase, rejected that argument. *Jansen*, slip op. at 14. Citing, *inter alia*, *Rapoport v. Dement*, 254 F.3d 1053 [59 USPQ2d 1215] (Fed. Cir. 2001), the court then construed the phrase "treating or preventing macrocytic-megaloblastic anemia" to require that, in order to infringe the patent, the human subject of the claimed method take the compound with the intent of treating or preventing macrocytic-megaloblastic anemia. *Jansen*, slip op. at 16. Because the court found no evidence of such intent or purpose on the part of Rexall's customers, the court granted summary judgment of noninfringement. *Id.* at 16-17.

Jansen timely appealed to this court, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Summary judgment is appropriate if "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). We review a district court's grant of a motion for summary judgment *de novo*. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 [47 USPQ2d 1272] (Fed. Cir. 1998).

A determination of patent infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted . . . [Second,] the properly construed claims are compared to the allegedly infringing device." *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 [46 USPQ2d 1169] (Fed. Cir. 1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 [34 USPQ2d 1321] (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 [38 USPQ2d 1461] (1996), that we review *de novo*. *Cybor*, 138 F.3d at 1456. Step two, comparison of the claim to the accused device, requires a determination that every claim limitation or its equivalent is found in the accused device. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 [41 USPQ2d 1865] (1997). Those determinations are questions of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 [48 USPQ2d 1674] (Fed. Cir. 1998).

On appeal, Jansen first argues that the court improperly construed the claims. More specifically, he contends that the court's construction improperly added to the claims an intent element, which is contrary to law as well as contrary to the ordinary meaning of the claim language, which does not suggest that the infringer's state of mind is relevant. Nor does the '083 patent's prosecution history, according to Jansen, suggest that the infringer's state of mind is relevant. He also argues that *Rapoport* does not support the court's view that a direct infringer must purposefully perform the claimed method, and that in any event *Rapoport* is distinguishable because that case, unlike this case, did not involve a claim to a method of prevention of a disease. According to Jansen, the phrase "a human in need thereof" encompasses a person who does not know that his or her serum levels of folic acid and vitamin B_{12} are adequate. Jansen secondly argues that he presented sufficient evidence of infringement to avoid summary judgment. According to Jansen, Rexall's formulation and labeling are circumstantial evidence of direct infringement by Rexall's customers.

Rexall responds that the court's claim construction does not add an intent element to the claims except as required by the particular language of the claims themselves. Rexall also contends that, just as in *Rapoport*, the claims in the '083 patent should be interpreted to require that the target group ("human[s] in need thereof") practice the method for the stated purpose ("treating or preventing macrocytic-megaloblastic anemia"), especially where, as here, the prosecution history reveals that both limitations were added for patentability. According to Rexall, a "human in need thereof" is someone either suffering from macrocytic-megaloblastic anemia or at a recognized risk, such as by medical diagnosis, of developing that condition. Rexall also responds that there is no evidence that it markets its product to the target group for the claimed purpose; on the contrary, it contends that it markets its product only for regulation of blood homocysteine levels. Rexall further contends that, even if there were some evidence of direct infringement by its customers, it is not liable for indirect infringement, for it has not intended to cause infringement and there are substantial noninfringing uses of its product, thereby negating inducement of and contributory infringement.

We begin our claim construction, as always, with the ordinary meaning of the claim language. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1341 [60 USPQ2d 1851] (Fed. Cir. 2001). That language requires that the method be performed on "a human in need thereof" and that the method be used "for treating or preventing macrocytic-megaloblastic anemia." The parties do not dispute what "macrocytic-megaloblastic anemia" means; instead, they dispute how the "treating or preventing" phrase and the "to a human in need thereof" phrase should be read. The issue reduces to whether such a human must know that he is in need of either treatment or prevention of that condition.

A similar issue arose in *Rapoport*, an interference proceeding before the PTO's Board of Patent Appeals and Interferences. The count in that case read as follows:

> A method *for treatment of sleep apneas* comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof *to a patient in need of such treatment* . . . .

254 F.3d at 1056 (emphases added). On appeal we gave weight to the ordinary meaning of the preamble phrase "for treatment of sleep apneas," interpreting it to refer to sleep apnea, *per se*, not just "symptoms associated with sleep apnea." *Id.* at 1059. Rapoport argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. *Id.* at 1061. We rejected that argument, stating, "There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition*." *Id.* (emphasis added). Thus, the claim was interpreted to require that the method be practiced

with the intent to achieve the objective stated in the preamble.

[1] Just as in *Rapoport*, it is natural to interpret the nearly parallel language in the '083 patent claims in the same way. In both *Rapoport* and this case, the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone "in need." In both cases, the claims' recitation of a patient or a human "in need" gives life and meaning to the preambles' statement of purpose. *See Kropa v. Robie*, 187 F.2d 150, 152 [88 USPQ 478] (CCPA 1951) (stating the rule that a preamble is treated as a limitation if it gives "life and meaning" to the claim). The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed. We need not decide whether we would reach the same conclusion if either of the "treating or preventing" phrase or the "to a human in need thereof" phrase was not a part of the claim; together, however, they compel the claim construction arrived at by both the district court and this court.

Our conclusion as to the meaning of the claims is bolstered by an analysis of the prosecution history. The prosecution history is often useful to ascertain the meaning of the claim language. Indeed, claims are not construed in a vacuum, but rather in the context of the intrinsic evidence, *viz.*, the other claims, the specification, and the prosecution history. *See DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1327 [57 USPQ2d 1889] (Fed. Cir. 2001). In this case, the "treating or preventing macrocytic-megaloblastic anemia" phrase and the "to a human in need thereof" phrase were added to gain allowance of the claims after almost twenty years of repeatedly unsuccessful attempts to gain allowance of claims without those phrases. We must therefore give them weight, for the patentability of the claims hinged upon their presence in the claim language. *See Smith v. Magic City Kennel Club, Inc.*, 282 U.S. 784, 790 (1931) ("The applicant[,] having limited his claim by amendment and accepted a patent, brings himself within the rules that if the claim to a combination be restricted to specified elements, all must be regarded as material, and that limitations imposed by the inventor, especially such as were introduced into an application after it had been persistently rejected, must be strictly construed against the inventor and looked upon as disclaimers."). Furthermore, because both phrases were added simultaneously to overcome the same rejection, they should be read together, meaning that the word "thereof" in the phrase "to a human in need thereof" should be construed to refer to the treatment or prevention of macrocytic-megaloblastic anemia. Finally, that "need" must be recognized and appreciated, for otherwise the added phrases do not carry the meaning that the circumstances of their addition suggest that they carry. In other words, administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia is not practicing the claimed method, because Jansen limited his claims to treatment or prevention of that particular condition in those who need such treatment or prevention. Thus, the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B_{12} must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.

[2] Given that claim construction, we turn to the issue whether Jansen has raised a genuine issue of material fact regarding infringement. We conclude that he has not. Jansen has asserted indirect infringement by Rexall, premised on direct infringement by Rexall's customers. *See Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 [231 USPQ 474] (Fed. Cir. 1986) ("Absent direct infringement of the patent claims, there can be neither contributory infringement nor inducement of infringement." (citations omitted)). Jansen's theory of infringement is primarily based upon his construction of the claim that those who do not affirmatively know that they do not need to take steps to prevent or treat macrocytic-megaloblastic anemia are still "in need thereof." As explained above, that claim construction is incorrect. Jansen nonetheless asserts that he has circumstantial evidence of direct infringement by Rexall's customers under the claim construction we and the district court have adopted. Specifically, he contends that Rexall's formulation, having folic acid and vitamin B_{12} in such large quantities as his claims call for, as well as Rexall's labeling stating that "[i]t is especially important to take B-12 along with Folic acid because Folic acid can mask a B-12 deficiency," are evidence that some customers do knowingly take the Rexall product to treat or prevent macrocytic-megaloblastic anemia.

While Jansen is correct that it is theoretically possible that some of Rexall's customers do take the Rexall product knowingly to treat or prevent macrocytic-megaloblastic anemia, and therefore directly infringe his patent, his evidence is quite weak. In fact, he has shown no more than a theoretical possibility or "metaphysical doubt," which is insufficient to create a *genuine* issue of material fact. *See Anderson*, 477 U.S. at 261 (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). The district court's decision that there were no genuine issues of material fact on the question of infringement was therefore correct.

Use of an over-the-counter product like Rexall's is quite different from the use of a product pursuant to a prescription from a medical doctor. In the latter case, a prescription is evidence of a diagnosis and a knowing need to use the product for the stated purpose. Jansen does not have evidence of that in this case. Rexall's product is provided with a label stating that the product can be used for maintenance of blood homocysteine levels, and purchasers do not necessarily know that they are in need of preventing or treating macrocytic-megaloblastic anemia. Instead, Jansen has only conjecture that some purchasers of the Rexall product might meet the claim requirements. The district court therefore did not err in holding that he failed to present sufficient proof of infringement to create a genuine issue of material fact and to thereby avoid summary judgment of noninfringement.

CONCLUSION

The district court correctly construed the claims of the '083 patent and properly determined that Jansen did not present sufficient evidence to create a genuine issue of material fact relating to infringement by Rexall. Accordingly, we

AFFIRM.

Droz-Serrano v. Caribbean Records Inc.

U.S. District Court
District of Puerto Rico
No. 03-1114 (JAG)
Decided June 24, 2003

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[1] Infringement pleading and practice — Jurisdiction (§ 217.05)

JUDICIAL PRACTICE AND PROCEDURE

Jurisdiction — Subject matter jurisdiction — Federal question (§ 405.0702)

Federal district court lacks subject matter jurisdiction over plaintiff recording artist's action for breach of recording and management agreements, even though subject matter of agreements is copyrighted material, since action does not "arise under" federal copyright laws merely because it relates to product that is subject of copyright, since examination of pleadings clearly shows that present action is strictly contract dispute, and since Copyright Act need not be construed in case in which plaintiff's sole remedy is action for contract damages.

Action by Yesenia Droz-Serrano against Caribbean Records Inc. and Maritza Casiano for breach of recording and management agreements, and failure to pay royalties. On defendants' motion to dismiss for lack of jurisdiction. Granted.

Jose R. Franco-Rivera, San Juan, P.R., for plaintiff.

Edwin Prado-Galarza, San Juan, for defendants.

Garcia-Gregory, J.

Pending before this Court is defendants' motion to dismiss for lack of jurisdiction (Docket No. 5), as well as plaintiff's opposition to the motion (Docket No. 8). For the reasons discussed below, this Court GRANTS defendants' motion to dismiss.

Facts

Plaintiff in this action, Yesenia Droz-Serrano ("Droz") is a recording artist who